Docket No.: 1254-0328PUS1

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Kazuwa NAKAO et al.

Application No.: 10/594,920 Confirmation No.: 5293

Filed: September 29, 2006 Art Unit: N/A

For: THERAPEUTIC OR PROPHYLACTIC AGENT Examiner: Not Yet Assigned

FOR ARTHRITIS

INFORMATION DISCLOSURE STATEMENT (SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. <u>LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION</u>

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

a. Copies of cited U.S. patents and patent application publications are not included. Copies of foreign patent documents and non-patent literature are included.

Application No.: 10/594,920 Docket No.: 1254-0328PUS1 Some or all of the documents listed on the PTO-SB08 are not enclosed because h. they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. c. \$1,98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120: U.S. Appl. No(s) and U.S. Filing Date III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box) DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy. \boxtimes DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the b. relevance of all patents, publications, or other information listed that is not in the English language is as follows: An English language abstract is attached to JP 2003-104908 A. ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search c. report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3). OTHER - The following additional information is provided for the Examiner's d. consideration.

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Docket No.: 1254-0328PUS1 Application No.: 10/594,920 IV. FEES (check one box) This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required. b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required. This Information Disclosure Statement is being filed within three months of the c. filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. (This section is not to be used with RCE's.) This Information Disclosure Statement is being filed within three months of the d. date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required. e. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required. This Information Disclosure Statement is being filed before the mailing date of a X f. first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p). This Information Disclosure Statement is being filed before the mailing date of a g. Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)). No statement: therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached. П

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or

Application No.: 10/594,920 Docket No.: 1254-0328PUS1 See the statement below. No fee is required. V. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box) The undersigned hereby states that: Each item of information contained in the IDS was first cited in any Я. communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or П b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS. d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

Application No.: 10/594,920 Docket No.: 1254-0328PUS1

VI.	PAYMENT	OF FFFS	(check one box)
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The required fee is listed on the attached Fee Transmittal.

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If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: January 16, 2007 Respectfully submitted,

Gerald M Murphy, Jr.

Registration No.: 28,977

BIRCH, STEWART, KOLASCH & BIRCH, LLP 8110 Gatehouse Road

Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant

Attachment(s):

PTO-SB08 Documents

Foreign Search Report

Fee

Other:

PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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•				Art Unit	N/A	
	(Use as many sheets as necessary)			Examiner Name	Not Yet Assigned	
Sheet	1	of	1	Attorney Docket Number	1254-0328PUS1	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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Examiner Initials*	No.1	Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Date MM-DD-YYYY	Applicant of Cited Document	or Relevant Figures Appear	۳
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NON PATENT LITERATURE DOCUMENTS					
Examiner Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, dity and/or country where published.					
	CA	JOHNSON et al., J. of Biological Chemistry, Vol. 278, No. 21, pp. 18824-18832, (2003).			
	СВ	KIEMER et al., Endocrinology, Vol. 143, No. 3, pp. 846-852, (2002).	_		
	CC	YASODA et al., Nature Medicine, Vol. 10, No. 1, pp. 80-86, (2004).			

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date Considered
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¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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For THERAPEUTIC OR PROPHYLACTIC AGENT Examiner: Not Yet Assigned

FOR ARTHRITIS

LETTER

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir

Enclosed herewith are copies of the documents that were cited in the International Search Report and listed on the Form PTO-SB08 filed with the Information Disclosure Statement on September 29, 2006.

The PTO is requested to make these documents of record in the file of the present application and to return the initialed Form PTO-SB08 to the undersigned.

Application No.: 10/594,920 Docket No.: 1254-0328PUS1

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: January 16, 2007 Respectfully submitted,

Gerald M. Murphy, Jr. Registration No. 28,977

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatchouse Road Suite 100 East P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000 Attorney for Applicant

Attachments: Documents cited in Search Report (11)

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			U.S. PA	TENT DOCUMENTS	***************************************
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
indiale."	No.	Number-Kind Code ² (#Inown)	MM-DD-YYYY	Applicant of Otted Document	Rolevant Passages or Relevant Figures Appear
	AA'	US-2003/0068313-A1	06-01-2004	Nakao	
	A8*	US-6,743,425-A1	06-01-2004	Nakao et al.	
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	88**	JP-2002-356437-A	12-13-2002	<u> </u>	V.,	ISR
	BC"	JP-59-51221-A	03-24-1984	\$27/7		ISR
	80"	WO-02/087620-A1	11-07-2002	7/1		ISR
	BE**	JP-4-74198-A	03-09-1992	***	17	ISR
	BF**	JP-4-327598-A	11-17-1992		~~~	ISR
	BG**	JP-11-196873-A	07-27-1999			ISR

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	CA**	Yasato KOMATSU et al., Clinical Calcium, 2003, 13(12), pages 1578 to 1581	ISR
	C8**	YASODA, A et al., J. Biol. Chem., 1998, 273(19), pages 11595 to 11700	ISR
	CC**	Yasato KOMATSU, Heisei 15 Nendo Sokatsu Buntan Kenkyu Hokokusho (Kosei Rodo Kagaku Kenkyuhi Hojokin Human Genome Saisei Iryo Nado Kenkyu Jigyo), 2004, March, jeagas 10 to 13	ISR
	CD.	Hiroshi KAWAGUCHI, Journal of Clinical Medicine, 2005, 63 (Zokango 1), pages 676 to 679	ISR

EXAMPLE: Initial if interests considered, whether or not citation is in conformance with MPEP 608. Draw line brough citation if not in conformance and not considered, include copy of this form with not commitment to applicant. "CITE: NO: Those documenting, which are mainted with an obusing satisfact," must be the Citation of the sen on application relief upone in this sentence for the ware previously citation for an authorities the Orlice in a prior application relief upone in this sentence for an application relief upone in this sentence for an application relief upone. earlier filtrig date under 35 U.S.C. 120.

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